

**United States Court of Appeals
for the Federal Circuit**

ALNYLAM PHARMACEUTICALS, INC.,
Plaintiff-Appellant

v.

MODERNA, INC., MODERNATX, INC., AND MODERNA US, INC.,
Defendants-Appellees.

*Appeal from the United States District Court for the District of Delaware,
Case Nos. 1:22-cv-0035-CFC, 1:22-cv-00925-CFC, Judge Colm F. Connolly*

**BRIEF OF BIONTECH SE, BIONTECH MANUFACTURING GMBH, PFIZER
INC., AND PHARMACIA & UPJOHN CO. LLC AS *AMICI CURIAE* IN SUPPORT
OF DEFENDANTS-APPELLEES AND AFFIRMANCE**

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**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT****CERTIFICATE OF INTEREST****Case Number** 2023-2357**Short Case Caption** Alnylam v. Moderna**Filing Party/Entity** BioNTech SE and BioNTech Manufacturing GmbH**Instructions:**

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 03/08/2024Signature: /s/ Charles B. KleinName: Charles B. Klein

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. <input type="checkbox"/> None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. <input type="checkbox"/> None/Not Applicable
BioNTech SE		N/A
BioNTech Manufacturing GmbH		BioNTech SE

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable

☐ Additional pages attached

Charles B. Klein	Jovial Wong	Claire Fundakowski

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☒ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☒ None/Not Applicable

☐ Additional pages attached

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT****CERTIFICATE OF INTEREST****Case Number** 2023-2357**Short Case Caption** Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.**Filing Party/Entity** Pfizer Inc.**Instructions:**

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Date: 03/08/2024Signature: /s/ Sara Tonnies HortonName: Sara Tonnies Horton

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Pfizer Inc.		N/A
Pharmacia & UpJohn Co. LLC		Pfizer Inc.

☐ Additional pages attached

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I. STATEMENT OF INTEREST

Amici are biotechnology and pharmaceutical companies that discover and develop innovative medicines for human diseases. During the height of the recent pandemic, Amici worked to develop a breakthrough COVID-19 vaccine, which was authorized by the FDA on December 11, 2020.

Plaintiff Alnylam sued Amici for patent infringement, alleging that the lipid nanoparticle technology used in Comirnaty® infringes the same patents that have been asserted against Moderna and at issue here. The case is ongoing in the District of Delaware under the consolidated case caption *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc. et al.*, 22-cv-336-CFC. Due to the overlapping patents and disputed claim terms between the cases against Amici and Moderna, the district court consolidated the *Markman* hearing giving rise to the instant appeal.

Pursuant to Federal Rule of Appellate Procedure Rule 29(c)(5)(A)-(C), Amici confirm that no party's counsel authored this brief in whole or in part, nor has any counsel, party or third person other than Amici made any monetary contribution intended to fund the preparation or submission of this brief. Amici filed this brief with the consent of both parties.

II. ARGUMENT

Amici agree with Moderna that the district court correctly construed the terms “branched alkyl” and “branched C₁₀-C₂₀ alkyl.” In deciding this appeal, however,

Amici ask the Court to exercise caution to avoid reaching the merits of how to construe a closely related claim term at issue solely in a related case, i.e., “R₁₃ is a branched C₁₀-C₂₀ alkyl.”

Amici are defendants in ongoing patent litigation brought by Alnylam in the District of Delaware, *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al.*, 22-cv-336-CFC. *See* Alnylam Br. at 1. That case concerns the same asserted patents, and Amici participated in the consolidated *Markman* hearing giving rise to this appeal. While the district court adopted Moderna’s proposed constructions of “branched alkyl” and “branched C₁₀-C₂₀ alkyl,” the district court did not adopt Amici’s proposed construction of the related claim term “R₁₃ is a branched C₁₀-C₂₀ alkyl.” *See* Alnylam Br. at 32-33 (citing Appx3-6; Appx5519-5522).

Amici’s proposed construction for that term tracks the construction of “branched C₁₀-C₂₀ alkyl” adopted by the district court with one material clarification: the structural requirements for the “branched C₁₀-C₂₀ alkyl” group must occur within the “R₁₃” group. Under Amici’s proposed construction, for the R₁₃ group to be “a branched C₁₀-C₂₀ alkyl,” one carbon atom in the group must be bound to at least three other carbon atoms *within* R₁₃. In other words, Amici’s position is that the branching contemplated by “branched alkyl”—binding to three other carbons—must all occur within the R₁₃ group and one of those carbons cannot be in the M¹ group.

Whether one of the three bound carbons in “branched alkyl” can be within the M¹ group is not an issue that the Court needs to resolve in order to address the parties claim construction dispute in this appeal. In fact, Alnylam has represented to the Court that the dispute as to Amici’s proposed construction for “R₁₃ is a branched C₁₀-C₂₀ alkyl” is “not germane to infringement or invalidity claims raised with respect to Moderna” and has “no bearing on the operative scope of the claim.” Alnylam Br. at 33 n.11 (quoting *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1372–73 (Fed. Cir. 2016)). And as Moderna explains, for both the —OC(O)— and —C(O)O— orientations, it is possible for all three bound carbons to be within the R₁₃ group without relying on carbons within the M¹ group. Moderna Br. at 52 (depicting three carbons within the green boxes).

Amici request that the Court decline to consider in this appeal the merits of whether a carbon from within the M¹ group can satisfy the district court’s constructions requiring one carbon atom in the group “is bound to at least three other carbon atoms.” As this Court has explained, “only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.” *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). The construction of “R₁₃ is a branched C₁₀-C₂₀ alkyl” is not in controversy and the Court need not reach this issue to construe “branched alkyl” or “branched C₁₀-C₂₀ alkyl.” See Alnylam Br. at 33 n.11. Moreover, reaching this issue now in the absence of

full briefing could deny Amici a fair opportunity to later argue the construction of the “R₁₃” term on appeal.

III. CONCLUSION

With the context described above, Amici support Moderna’s position that the district court’s constructions of “branched alkyl” and “branched C₁₀-C₂₀ alkyl” should be affirmed.

Respectfully submitted,

/s/ Charles B. Klein

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CERTIFICATE OF SERVICE

I certify that on March 8, 2024, the foregoing brief was filed with the Clerk of Court and caused to be served on all parties through the Court's electronic filing system. I further certify that all parties required to be served have been served.

/s/ Charles B. Klein

CHARLES B. KLEIN

*Counsel for Amici Curiae BioNTech SE
and BioNTech Manufacturing GmbH*

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and Federal Circuit Rule 32(b) because it contains 763 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

/s/ Charles B. Klein

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March 8, 2024